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10/698,591

10/31/2003

David E. Wolf

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7590

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ALLISON JOHNSON, P.A.  
LAKE CALHOUN EXECUTIVE CENTER  
3033 EXCELSIOR BLVD., SUITE 467  
MINNEAPOLIS, MN 55416

EXAMINER

RAMILLANO, LORE JANET

ART UNIT

PAPER NUMBER

1743

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/698,591

Applicant(s)

DAVID E. WOLF

Examiner

Lore Ramillano

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-45 and 47-49 is/are pending in the application.
- 4a) Of the above claim(s) 25-45 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24, 48 and 49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/2/04, 4/18/05.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of claims 1-24 and 48-49 (Group I) in the reply filed on 4/10/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 25-45 and 47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/10/07.

### *Claim Objections*

3. Claims 25-45, and 47 are objected to because of the following informalities:

The numbering of claims 47-49 should be renumbered to claims 46-48 since applicant appeared to make a mistake in numbering claims 47-49. The status identifiers of claims 25-47 should be changed to withdrawn.

Appropriate corrections are required.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 12, 48, and 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- b) attaching a label comprising a first component of a non-radiative fluorescence resonance energy transfer donor-acceptor pair to an analyte-analogue;
- c) selecting an analyte binding ligand from a combinatorial library, said analyte binding ligand being capable of binding with said analyte-analogue;
- d) attaching a label comprising a second component of a non-radiative fluorescence resonance energy transfer donor-acceptor pair to said analyte binding ligand; and
- e) encapsulating said labeled analyte binding ligand and said labeled analyte-analogue,

said sensor exhibiting either

non-radiative fluorescence resonance energy transfer when said analyte-analogue is bound to said analyte binding ligand, and a change in non-radiative fluorescence resonance energy transfer when said analyte-analogue is not bound to said analyte binding ligand, or

being free from non-radiative fluorescence resonance energy transfer when said analyte-analogue is bound to said analyte binding ligand, and exhibiting non-radiative fluorescence resonance energy transfer when said analyte-analogue is bound to said analyte binding ligand.

\* \* \* \* \*

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Claim 12 recites the limitation "the analyte comprises glucose." There is insufficient antecedent basis for this limitation in the claim.

Claim 23 recites the limitation "the human serum albumin is glycosylated." There is insufficient antecedent basis for this limitation in the claim.

The claim language of claims 48 and 49, "sensor exhibits less than 1% leakage of its fluorescence reagent when stored for two weeks at 37 degrees Celsius in pH 7.4 10 mM HEPES/0.15 M saline solution" is indefinite because it is unclear how the claim language structurally further defines applicant's invention.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1-5, 12, 13, 48, and 49** are rejected under 35 U.S.C. 102(b) as being anticipated by Zentner (US 4814183), and in light of Sharma (US 5610233).

Zentner discloses a core comprising hydrogel (i.e. water insoluble, nondiffusible resin entity, 2, fig. 1a); fluorescence reagent disposed in the core is mobile in the core (i.e. column 5, lines 65-68); a semipermeable coating surrounding the core (i.e. cellulose acetate, column 9, line 30 to column 10, line 28); and a biocompatible coating (i.e. 7, fig. 1a) surrounding the semipermeable coating.

Zenter further discloses the following: an analyte comprising glucose (i.e. column 8, lines 44-63); and the sensor is capable of detecting the analyte based on nonradiative fluorescence resonance energy transfer (i.e. column 5, lines 33-49).

Zentner inherently discloses a semipermeable coating comprising a polydisperse polymer having a weight average molecular weight from about 4 kDa to about 18 kDa and a polydispersity index greater than 1 because Zentner's semipermeable coating is made of cellulose acetate, which Sharma discloses as having a weight average molecular weight of 10 to 60 kDa and a polydispersity index in the range of 1.05 to 2.0 (i.e. column 1, line 65 to column 2, line 9; column 3, lines 1-5).

8. **Claims 1-13, 48, and 49** are rejected under 35 U.S.C. 102(e) as being anticipated by Wolf et al. ("Wolf '503," US Pub. No. 20030170278) in light of Chen et al. ("Chen," US Pub. No. 2003/0229185).

Wolf '503 discloses a core comprising hydrogel; fluorescence reagent disposed in the core is mobile in the core; a semipermeable coating (i.e. polylysine) surrounding the core, which has a weight average molecular weight from about 4 kDa to about 18 kDa; and a biocompatible coating surrounding the semipermeable coating (i.e. [0005], [0036]-[0042]).

Wolf '503 further discloses the following: a sensor having a diameter between 1 mm to 3 mm (i.e. [0005]); an analyte comprising glucose (i.e. fig. 4); and the sensor is capable of detecting the analyte based on nonradiative fluorescence resonance energy transfer (i.e. [0037]).

Wolf '503 inherently discloses a semipermeable coating comprising a polydisperse polymer having a polydispersity index greater than 1 because Wolf '503 semipermeable coating is made of polylysine, which Chen discloses as having a polydispersity index greater than 1 (i.e. [0080]).

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***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. **Claims 6-11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zentner, in light of Sharma, and in view of Tsang et al. ("Tsang," US 4663286).

The disclosure of Zentner in light of Sharma is disclosed above. Zentner in light of Sharma does not specifically disclose a polydisperse polymer comprising polylysine and having a diameter from about 1 to 3 mm.

Tsang discloses a technique for encapsulating a core material within an intracapsular volume defined by a membrane. Tsang prefers encapsulating the core material with a polycationic polymer, such as polylysine, because the charge density of polycationic polymers has a material effect on porosity control of the capsules (i.e. column 2, line 65 to column 3, line 39). It would have been obvious to a person of ordinary skill in the art to modify Zentner, in light of Sharma, by having a semi-permeable membrane made of polylysine because it would be beneficial to have an alternate type of membrane, which is selectively permeable to solutes that are not permeable to Zentner's semipermeable membrane.

Furthermore, Tsang discloses making capsules, which preferably are between 50 microns and a few millimeters in diameter (i.e. column 5, lines 18-21). It would have been obvious to a person of ordinary skill in the art to modify Zentner, in light of Sharma, by making capsules which range from 50 microns to a few millimeters in diameter because it would be easier for the consumer to ingest a relatively smaller-sized capsule.

13. **Claims 14-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zentner, in light of Sharma, and in view of Leung et al. ("Leung," US Pub. No. 2002/0064794).

The disclosure of Zentner in light of Sharma is disclosed above. Zentner in light of Sharma does not specifically disclose a fluorescence reagent comprising an energy acceptor and an energy donor, which consists of carbocyanine dyes and albumins.

Leung discloses in one embodiment comprising a biological polymer such as a protein that is labeled with at least a second fluorescent dye to form an energy-transfer pair (i.e. energy



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acceptor and an energy donor) (i.e. [0067]); carbocyanine dye having an excitation maximum at about 581 or 578 nm and an emission at about 596 or 603 nm, concanavalin A, a second carbocyanine dye having an excitation maxima at about 650 or 675 nm and an emission maxima at about 665 or 694 nm, and human serum albumin (i.e. [0004], Table 3, Example 94); and molar ratios (i.e. Table 3).

It would have been obvious to a person of ordinary skill in the art to modify Zentner, in light of Sharma, by incorporating a fluorescence reagent comprising an energy acceptor and an energy donor, which consists of carbocyanine dyes and albumins because it would be beneficial to have a system of determining the effectiveness of Zentner's invention by performing tests on the consumer after the consumer has digested the capsule.

14. **Claims 14-19 and 24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf '503, in light of Chen, and in view of Chick et al. ("Chick," US 6040194).

The disclosure of Wolf '503, in light of Chen is disclosed above. Wolf '503, in light of Chen does not specifically disclose a fluorescence reagent comprising an energy acceptor and an energy donor, which consists of carbocyanine dyes, albumins, and concanavalin A.

Chick discloses a fluorescent reagent comprising an energy acceptor and an energy donor (i.e. carbocyanine dyes, rhodamine dyes); and a carbocyanine dye having an excitation maximum at about 581 or 578 nm and an emission at about 596 or 603 nm, concanavalin A (i.e. glucose binding protein), a second carbocyanine dye having an excitation maxima at about 650 or 675 nm and an emission maxima at about 665 or 694 nm, and human serum albumin (i.e. glycosylated substrate). (i.e. column 2, line 30 to column 5, line 15; column 11, lines 36-47).

It would have been obvious to a person of ordinary skill in the art to modify Wolf '503, in light of Chen, by incorporating a fluorescence reagent comprising an energy acceptor and an

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energy donor, which consists of carbocyanine dyes, albumin, and concanavalin A because it would be beneficial to use a fluorescent reagent that is reliable, reusable, easy to use, and can be easily modified into an in vivo sensor (i.e. column 2, lines 28-30).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lore Ramillano  
Examiner  
Art Unit 1743

  
BRIAN R. GORDON  
PRIMARY EXAMINER